UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

ARTHUR RAY BOWLING, *et al.*,	)	Case No. C-1-91-256
	)	
Plaintiffs,	)	Judge Timothy S. Black
	)	
v.	)	
	)	
PFIZER, *et al.*,	)	
	)	
Defendants.	)	

AMENDED ORDER APPROVING AMENDMENT AND DISTRIBUTION

Before the Court is the Joint Motion for Final Approval of Proposed Amendment to the Settlement and the Proposed Distribution (Doc. #3136) ("Joint Motion").[1]

In considering the Joint Motion, the Court also has taken into consideration the presentations at the hearing on October 29, 2015, as well as the following prior filings in this case, which are relevant to the proposed Amendment and distribution: Trustee's Position on Funds Needed for the Administration of the Bowling-Pfizer Settlement (Doc. #2821); Report and Recommendations of the Supervisory Panel re: the Guidelines, the Future Scope of Work of the Panel and Recommendations for the Use of Any Remaining Money in the Patient Benefit Fund (Doc. #2871); Response of Class Counsel and Public Citizen to the Report and Recommendations of the Supervisory Panel re: the Guidelines, the Future Scope

[1] This Amended Order amends the Court's previous Order Approving Amendment and Distribution (Doc. 3138) solely to correct two minor typographical errors on pages 30 and 31 of the Order.

of Work of the Panel and Recommendations for the Use of Any Remaining Money in the Patient Benefit Fund (Doc. #2881); Response of Special Counsel to the Report and Recommendations of the Supervisory Panel re: the Guidelines, the Future Scope of Work of the Panel and Recommendations for the Use of Any Remaining Money in the Patient Benefit Fund (Doc. #2883); Response of Pfizer to the Report and Recommendation of the Supervisory Panel re: the Guidelines, the Future Scope of Work of the Panel and Recommendations for the Use of Any Remaining Money in the Patient Benefit Fund (Doc. #2884); Report and Recommendations of the Supervisory Panel re: the Guidelines, the Future Scope of Work of the Panel and Recommendations for the Use of Any Remaining Money in the Patient Benefit Fund [*sic*] (Doc. #2889); Notice of Filing of Financial Information for the Bowling-Pfizer Heart Valve Litigation Settlement Fund for the Years 2010, 2011, 2012 and 2013 (Doc. #2937); and Joint Motion for Preliminary Approval of Proposed Amendment to the Settlement, and for Approval of Proposed Notices to the Class and Proposed Notice Procedures (Doc. #3100).

The principal issues raised by the Joint Motion and the other filings listed above are the final approval of the proposed Amendment to the Settlement Agreement in this case ("the proposed Amendment") and of the proposal by Class Counsel to distribute money from the Patient Benefit Fund directly to members of the Settlement Class ("the proposed distribution"). For the reasons set forth below, the Court approves both the proposed Amendment and the proposed distribution.

FACTUAL AND PROCEDURAL BACKGROUND

A. The Settlement Agreement

The original Settlement Agreement in this case was signed on January 23, 1992. The parties thereafter executed various modifications and supplements in response to class members' objections to the Settlement Agreement. Some objections were resolved through modifications or supplements executed before or during the original fairness hearing, which took place in June and July of 1992 before Judge Spiegel. Objections that remained unresolved following the fairness hearing were highlighted in an interim opinion issued by Judge Spiegel. *Bowling v. Pfizer, Inc.*, 143 F.R.D. 138 (S.D. Ohio 1992). For example, class members objected to the lack of any cash compensation for spouses of BSCC patients. Ultimately, $10 million was added to the fund for the spouses. *Id.* at 170. The parties executed a range of other beneficial amendments (*e.g.*, liberalized benefits for certain foreign OSF claimants).

Finding it to be "fair, adequate, and reasonable," Judge Spiegel approved the "Supplemented Agreement of Compromise and Settlement" (Doc. #245) in an order dated August 19, 1992 (Doc. #250). In his order approving the Settlement Agreement, Judge Spiegel provided the following background information regarding the claims asserted in this case:

> From 1979 to 1986, Shiley, a wholly-owned subsidiary of Pfizer, produced thousands of Bjork-Shiley convexo/concave heart valves. Somewhere between 50,000 and 100,000 of these valves were implanted in patients from all over the world. It is now thought that about 450 of these heart valves have fracture, resulting in approximately 300 fatalities. Critics of Pfizer-Shiley

> have alleged that Bjork-Shiley convexo/concave heart valves have a tendency to fracture because of design and manufacturing defects. Pfizer-Shiley denies any design or manufacturing defects and claims that its heart valves are not any more likely to fracture than other heart valves available on the market.

Id. at 6-7.

In the same order, Judge Spiegel mentioned several features of the Settlement Agreement that are relevant to the proposed Amendment currently before the Court, including the following:

- "The settlement offers benefits to class members who have the [Bjork-Shiley convexo/concave] artificial valves and their spouse from funds totaling from $165 million to $215 million, as well as certain other payments without any monetary limit…."
- "A fund of $75 million will be established…."
- "The fund will pay for (a) research to develop diagnostic techniques to identify valve recipients who may have a significant fracture risk, and (b) research to characterize or reduce the risk of valve replacement surgery…."
- "The fund will pay for certain expenses incurred by class members for diagnostic testing services to identify recipients who have a significant risk of fracture when the diagnostic techniques are developed or accepted by the FDA…."
- "The Supervisory Panel will allocate research funds, administer the testing program and select entities to perform research services…."
- "Payments will be made from the $75 million fund for valve replacement surgery which qualifies under the guidelines established by the Supervisory Panel…."
- "Even if the $75 million is exhausted, Pfizer will remain obligated to continue to pay benefits for qualifying valve replacement surgery…."

Id. at 10-12. Addressing the provisions of the Settlement Agreement related to the $75 million Patient Benefit Fund, Judge Spiegel expressed confidence "that the research money

will be spent for the benefit of the class" and observed that "in no event may the research money revert to Pfizer-Shiley." *Id*. at 56.

B. The Settlement Class

As of January 23, 1992, the date the original Settlement Agreement was signed, approximately 84,000 individuals had been implanted with the Bjork-Shiley convexo-concave ("BSCC") artificial heart valve.

The Settlement Class currently includes anyone who had been implanted with a BSCC artificial heart valve as of January 23, 1992 *and* is still alive, *and* that person's spouse *if* the spouse was married to the implantee on that date *and* still is married to him or her.

C. The Proposed Amendment

Section 5 of the Settlement Agreement established the Patient Benefit Fund. Under the Settlement Agreement, Shiley and Pfizer devoted $75 million to that fund to support programs, including valve-related medical research aimed at developing a non-invasive medical device that would diagnose fracture-prone BSCC valves.

Paragraph 5.5 of the Settlement Agreement anticipated that at some point the Supervisory Panel might determine that research no longer would be useful and that the remaining money in the Patient Benefit Fund should be devoted to other uses beneficial to the Settlement Class. In this regard, Paragraph 5.5 currently states as follows:

> If the Supervisory Panel at any time determines that any money remaining in the Patient Benefit Fund cannot productively be spent for the specific purposes set forth herein, including payment of benefits for valve replacement surgery, it may recommend to the Court that such remainder should therefore be devoted to some other purpose for the benefit of the

> Settlement Class (other than direct distribution to the class members). Subject to the approval of the Court, the Panel shall then direct the disposition of the remainder of the Fund. At such time, all of Shiley's and Pfizer's obligations under this section 5 shall cease, except to make any remaining unpaid installments (up to a maximum of $75 million) into the Patient Benefit Fund.

Settlement Agreement, p. 18.

When the Supervisory Panel determined in 2010 that valve-related research no longer would be useful, it invoked Paragraph 5.5 of the Settlement Agreement. Doc. #2670. Subsequent to that, however, in 2014, at the urging of Class Counsel, Pfizer, Public Citizen, and the Special Master/Trustee, Judge Weber approved a Cleveland Clinic research study entitled "Assessment of Outlet Strut Status on Bjork-Shiley Prosthetic Valves Using High Resolution X-Ray Computed Tomography." Doc. #3000. At the time of its approval, the Cleveland Clinic study was viewed as a test—in all probability the last test—of the Supervisory Panel's conclusion that further research into diagnostic tests would not be useful. In September 2014, the data obtained from that study confirmed that the imaging technique studied could not detect a fractured valve, so the decision was made not proceed further with any research. No active research programs are underway.

The decision now before the Court is what to do with the remainder of the Patient Benefit Fund, currently $18,610,233.

As it now reads, Paragraph 5.5 of the Settlement Agreement would prohibit distributing money in the Patient Benefit Fund directly to the members of the class. Class Counsel and Pfizer have agreed on language for the proposed Amendment, the main

purpose of which is to remove this prohibition, so that money in the Patient Benefit Fund could then be distributed directly to class members.

The proposed Amendment, which Class Counsel and Pfizer jointly submitted to the Court for approval and which Special Counsel and Public Citizen also support, would eliminate a prohibition in current Paragraph 5.5,[2] which precludes "direct distribution" of money in the Patient Benefit Fund "to the class members." Eliminating this prohibition would permit a distribution of money in the Patient Benefit Fund directly to the members of the class.

In addition, the proposed Amendment addresses and provides for several other eventualities.

First, it provides that, "If the Supervisory Panel at any time determines that the money remaining in the Patient Benefit Fund cannot productively be spent for the specific purposes set forth in Paragraph 5.2, excepting subsection 5.2.3, the Panel shall recommend to the Court that the remainder of the Patient Benefit Fund be devoted to some other purpose for the benefit of the Settlement Class. Upon receiving such recommendation from the Panel under this Paragraph, the Court may either terminate the work of the Supervisory

[2] Due to a typographical error, the preamble on the copy of the proposed Amendment submitted for preliminary approval omitted certain words. The preamble stated that the Amendment would "[d]elete existing Paragraph 5.5 with the following new Paragraph 5.5 …." The preamble should have stated "Delete existing Paragraph 5.5 and replace it with the following new Paragraph 5.5 …." The notice to the class, however, made clear that under the Amendment new Paragraph 5.5 was to replace current Paragraph 5.5.

Panel or suspend it until, in the opinion of the Court, circumstances warrant further involvement by the Panel or any of its members."

Second, the Amendment provides that, "If the Court opts to terminate or suspend the work of the Supervisory Panel under this Paragraph 5.5, the Court may retain as a consultant any medical or scientific expert it deems necessary."

Third, the Amendment provides that, "If the Court approves the recommendation of the Supervisory Panel under this Paragraph 5.5, the Court may order that the remainder of the Patient Benefit Fund be distributed to some or all of the members of the Settlement Class."

Fourth, the Amendment provides that, if the Court orders a distribution to some or all of the members of the class, a sufficient amount of money will remain in the Patient Benefit Fund to cover the future costs of administering the settlement, which amount shall be approved by the Court (the "hold-back"). The Amendment states that the hold-back shall be:

> sufficient to cover the reasonable and foreseeable
>
> (a) costs of reimbursing qualified class members' uninsured expenses related to explant surgeries under subsection 5.2.3, including those who qualify under the Supervisory Panel's guidelines and those later diagnosed with single-leg fractures;
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> (b) fees and expenses of the Settlement Administrator;
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> (c) fees and expenses of the Special Master/Trustee;

(d) fees for any necessary tax return preparation and accounting and for a biennial review of the remaining funds by a qualified outside accounting firm;

(e) costs associated with administering, implementing, and/or enforcing the terms of the Settlement, including any additional expenses of the Supervisory Panel or its members and any further work that the Court might ask of the Panel or any of its members; and

(f) fees and expenses related to any distribution.

And, fifth, the proposed Amendment states that "Nothing in this Paragraph 5.5 shall affect Shiley's and Pfizer's obligations under Section 7 or any other provision of this Agreement, including the payment of 'additional or alternative benefits' referred to in Paragraph 5.6 and set forth thereafter; except that, if the Court orders that the remainder of the Patient Benefit Fund (minus the appropriate hold-back as described above) be distributed directly to some or all of the members of the Settlement Class, upon completion of that distribution all of Shiley's and Pfizer's obligations under subsection 5.3.3 of this Agreement shall cease. Notwithstanding any other provision of this Agreement, the provisions of this Paragraph 5.5 are controlling." This language means that if the Court approves the proposed Amendment, Shiley and Pfizer would continue to compensate class members for any individual valve-fracture claims. This language also means that Shiley and Pfizer would continue to pay the additional or alternative benefits referred to in section 5.6 of the Settlement Agreement. These additional or alternative benefits include payment of $38,000 for all miscellaneous costs and expenses relating to and following hospitalization for qualifying valve replacement surgery; payment for such class member's actual lost

income due to time lost from work (up to $1500 per week up to 16 weeks, and longer in the case of a class member who becomes disabled as a result of the surgery) to the extent not otherwise covered by workers' compensation, sick pay, disability, or other benefits; and other payments in the event such class member dies or becomes disabled as a result of qualifying valve replacement surgery.

To clarify further the ramifications of the Amendment, claims by eligible class members for reimbursement of the uninsured costs of qualifying valve replacement surgeries would be among the expenses paid out of the hold-back. Under subsection 5.3.3 of the Settlement Agreement, the uninsured costs of qualifying valve replacement surgeries currently are paid out of the Patient Benefit Fund, and Shiley and Pfizer currently would have an obligation to pay those uninsured costs if that fund ever ran out of money. Although this obligation would cease under the proposed Amendment, Class Counsel, Pfizer, Special Counsel, Public Citizen, and the Special Master/Trustee all maintain that the proposed amount of the hold-back—$1,619,835—would be sufficient to cover these and other costs, given the relatively minimal amounts that have been expended for that purpose in recent years.[3]

D. The Proposed Distribution and Hold-Back

If the Court approves the proposed Amendment, Class Counsel also asks the Court to approve a direct distribution to Settlement Class members of the money in the Patient

[3] Such reimbursements totaled about $1.3 million over the 23-year life of the settlement and $397,421.56 since 2001. But they have only totaled $107,953.88 over the past 12 years, and $3,083.97 over the past seven years.

Benefit Fund, minus the appropriate hold-back discussed above. Class Counsel propose that $16,990,398 of the $18,610,233 currently in the Patient Benefit Fund be distributed directly to the members of the class—in other words, a hold-back of $1,619,835. Class Counsel, Special Counsel, Public Citizen, and Pfizer have agreed on this as the appropriate hold-back. The Special Master/Trustee also concurs with the proposed amount of the distribution and hold-back.

If the Court approves this proposed distribution, Class Counsel have proposed that each living registered implantee class member would be eligible to receive a share of it, as would each living spouse of an implantee class member who was married to that implantee as of January 23, 1992 and who is still married to that implantee when the proposed distribution is approved.

Class Counsel have proposed that the total amount of money available for the qualifying spouses' aggregate awards ("the spouses' aggregate share") would be one-eighth of the total amount of money available for the qualifying implantees' aggregate awards ("the implantees' aggregate share"), just as with the original distribution. Under this proposal, each qualifying implantee would receive a larger percentage of the implantees' aggregate share than in the original distribution, and each qualifying spouse would receive a larger percentage of the spouses' aggregate share than in the original distribution. The reason for this is logical—there would be fewer eligible implantees and eligible spouses this time around due to deaths among implantee class members and deaths or divorces among spouse class members.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. The Court's Preliminary Approval Order and Compliance With It

The first step in the process of approving a proposed class action settlement—or, as in this case, an amendment to one—is commonly known as "preliminary approval." It warrants preliminary approval if it is within the range of what ultimately could be considered fair, reasonable, and adequate—a determination left to the sound discretion of the Court.[4] In its Order dated July 24, 2015 (Doc. #3111), the Court found that the proposed Amendment is within the range of what ultimately might be found to be fair, reasonable, and adequate. The Court thus preliminarily approved the proposed Amendment and directed that notice be issued to the class.

The original 1992 notice involved an extensive combination of worldwide first-class-mail and publication notice, which Judge Spiegel found met the demands of Rule 23 and due process. Although the original notice did not indicate that monetary payments would or could be made from leftover Patient Benefit Fund monies, it did inform class members that they would receive at least $80 million (and as much as $130 million) in cash, representing at least $2,500 per class member. *See Bowling v. Pfizer, Inc.*, 143 F.R.D. 141, 149 (S.D. Ohio 1992) (describing the original cash distribution aspect of settlement).[5] In fact,

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[4] *See In re Southern Ohio Correctional Facility*, 173 F.R.D. 205, 211 (S.D. Ohio 1997).

[5] It should be noted that the 1992 notice was not the only notice undertaken in this case. Beginning in 2005, the Court oversaw another significant notice program. Its specific purpose was to attract additional registrants so that they could avail themselves of settlement benefits. In June 2005, all class members registered with Medic Alert were notified. Later, in 2006, a similar notice was published in seven foreign and thirteen U.S.

each registered implantee-class member received $6,147, and each qualified spouse-class member received $1,009.

Although previous modifications of the Settlement Agreement before, during and after the original fairness hearing did not trigger any new class notices, and due process may not have required class notice in this instance, out of an abundance of caution the Court deemed it is advisable to provide class members with the best practicable notice of the proposed Amendment and the proposed distribution.

In the motion seeking preliminary approval, Class Counsel, Pfizer, Special Counsel, and Public Citizen proposed a long-form notice and short-form notice. They further recommended that the proposed long-form notice be mailed to every member of the class

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newspapers and was placed on the domestic and foreign newswires. In these notices, class members were informed that registering with the Claims Administrator would help them obtain future benefits and settlement-related information. The notice to the Medic Alert registrants, entitled "Last Mailed Notice to Register for Bjork-Shiley C/C Heart Valve Legal Settlement Benefits," provided the following boxed warning in bold type: "You must register to be eligible to receive important information and learn more about benefits available to you." It further informed the recipient that registration with Medic Alert alone was not necessarily sufficient to obtain the settlement's full benefits: "If you registered with Medic Alert or any other organization, you still need to register with the Claims Administrator." Similarly, the published notice, entitled in all capital letters "Important Notice to All Bjork-Shiley Convexo-Concave Heart Valve Implantees," "urge[d] [class members] to register as soon as possible with the Bowling Settlement Claims Administrator, if you have not already done so." It warned in bold type that "There will be no further formal notification issued about registration," and that "If you do not register, it may be impossible to contact you with information about your particular heart valve and about settlement benefits to which you may be entitled *or to which you may later be entitled to receive*." (Emphasis added.) As a result of the 2005-2006 notice program, 291 additional class members registered with the Claims Administrator 281 as a result of the Medic Alert notice and 10 as a result of the publication notice.

and that the short-form notice be posted on various websites. The Special Master/Trustee joined in these recommendations.

The long-form notice explained the proposed Amendment and the proposed distribution, including the dollar amounts that would be distributed and held back, and the approximate dollar amount that each class member could expect to receive under each proposal. That notice also adequately informed class members of the scheduled hearing and of their opportunity to comment on or object to the proposed Amendment and the proposed distribution before or at that hearing. It also properly advised class members on the importance of updating their personal information (*e.g.*, change of address, death of implantee or spouse, etc.) to help ensure the efficiency and accuracy of the proposed cash distribution, if one were to be ordered; and it adequately described the various means by which class members could do so (*i.e.*, online via a website, by email, by mail, or by calling the settlement administrator's office free of charge). For the Medic Alert registrants only, the proposed long-form notice properly explained that any distribution to a Medic Alert registrant would be contingent on the individual granting permission to the settlement administrator to add his or her name to the list of registered class members and provided directions on the various means by which Medic Alert registrants could grant such permission (again, online via a website, by email, by mail, or by calling the settlement administrator's office free of charge).

The Court approved the long-form notice and the proposed procedures for its dissemination in the Order dated July 24, 2015 (Doc. #3111).

The short-form notice proposed by Class Counsel and Pfizer and agreed to by all counsel and the Special Master/Trustee provided class members with a more limited amount of information about the proposed Amendment and distribution, while directing them to more complete information, including the long-form notice and the *Bowling/Pfizer* settlement website. The Court approved the short-form notice in the Order dated July 24, 2015 (Doc. #3111), requiring it to be posted on various websites, including "the *Bowling/Pfizer* website and relevant blogs or websites pertaining to health-related class actions, consumer law, or cardiology," and that it be sent "to the foreign medical societies and agencies that received earlier notices in this case or their successors."

On October 27, 2015, the Special Master/Trustee filed the Declaration of Nancy A. Johnson, President of CAC, the settlement administrator in this case. In her Declaration, Johnson stated the following with respect to the actions taken to comply with the Order of July 24:

> 5. Given the preceding information, I caused the following to occur as effort to fulfill the Notice requirements outlined in the Notice:
>
> a. On or before September 14, 2015, the "Notice Packet" was translated into 12 languages, attached hereto as Exhibit 1.
> b. On September 17, 2015, the U.S. Class Member List was updated using the National Change of Address system (NCOA), which updates the addresses for all persons and businesses who had moved in the previous four years and who had filed a change of address with the U.S. Postal Service for U.S. Class Members. Special postal software similar to NCOA was used for the International Class Member List;
> c. On September 17, 2015, the Notice, W9 and W9 Instructions were printed, personalized, and inserted into a #10 window

envelope (the "Notice Packet"). The Notice Packet was provided to three thousand two hundred and twenty-three (3,223) U.S. Settlement Class members and two hundred and thirty-one (231) Canadian Settlement Class members in the English language. The Notice and tax forms are attached hereto as Exhibit "1";

d. On September 17, 2015, the Notice, W8-BEN and W8-BEN Instructions were printed in 12 languages, personalized, and inserted into a #10 window envelope (the "Notice Packet"). The International Notice Packet was mailed to five thousand seven hundred and ninety (5,790) Settlement Class Members. The International Notice Packets in 12 languages is attached hereto as Exhibit "1"
e. Of the (9,244) Notice Packets that were mailed to Settlement Class Members, seven hundred eighty two (782) were for individuals on the Reconsideration List. The Reconsideration List consisted of Class Members who did not make a claim or receive any prior distributions, but wanted to be included should any future distributions take place. Their serial number had been verified against the serial numbers in our original database and were found to be a match. Marriage certificates were required in order for any spouse to receive a payment.
f. A list of the countries that the Notice Packet was mailed to is attached hereto as Exhibit "2".
g. On September 17, 2015, three thousand four hundred and fifty-four (3,454) Notice Packets, comporting with each of the individuals listed on the Class Member List for the U. S. and Canada were mailed, using first-class postage, at the U.S. Post Office in Eagan, Minnesota.
h. On September 17, 2015, five thousand seven hundred and ninety (5,790) International Notice Packets were mailed, using first-class postage, at Action Mailing Services, in Peterborough, U.K.
i. On September 24, 2015 an e-mail blast was sent to two hundred (200) country medical associations or societies for posting of the short form notice to their websites. Attached here to is Exhibit "3"

6. As of October 21, 2015, twenty-nine (29) Notice Packets were returned to CAC by the U.S. Postal Service with forwarding addresses. The

> Class Member List was subsequently updated with the new addresses and a Notice Packet was re-mailed to said Settlement Class Members at each of the new addresses.
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> 7. As of October 21, 2015, six hundred and two (602) Notice Packets have been returned to CAC by the U.S. Postal Service without forwarding addresses. A skip trace was performed and four hundred eighty-two (482) new addresses were found. The Class member List was subsequently updated with the new addresses and a Notice Packet was re-mailed to said Settlement Class Members at each of the new addresses. CAC will explore any available options for locating domestic Class Members whose packets were returned and whose addresses were not found through the skip tracing utilized thus far.
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> 8. As of October 21, 2015, fifty-two (52) foreign Notice Packets have been returned to CAC by the U.S. Postal Service without forwarding addresses. We have no means to do skip tracing on foreign mail so no further action was taken.

Declaration of Nancy A. Johnson (Doc. # 3134-1), ¶¶ 5-8.

Based on the Declaration of Nancy A. Johnson, the Court is satisfied that the Special Master/Trustee and the administrator complied with the July 24 Order to the best of their ability.

B. Final Approval of the Proposed Amendment and Distribution

1. Subject to an appropriate hold-back, a direct distribution represents the optimal use of the remaining funds.

Even though the parties, when they originally executed the Settlement Agreement, anticipated that the day could come when it no longer would be useful to devote money from the Patient Benefit Fund to diagnostic research and that another use for that Fund would have to be found, they also originally agreed that direct cash payments to class members would not be permitted. One might argue that this should be the last word on the

subject. It is important to note, however, that the parties specifically reserved the right to modify or amend their Settlement Agreement by mutual consent. *See* Paragraph 12.3 of the Settlement Agreement (permitting modifications or amendments in writing, signed by all parties, meaning Pfizer and the class). Indeed, the parties modified the Settlement Agreement multiple times before Judge Spiegel approved it. *See* Doc. #250, p. 3. It is, therefore, clearly within the capacity of these parties to modify or amend the terms of their Settlement Agreement to fit changed circumstances.

Any proposed amendment or modification is, of course, subject to this Court's approval. The question for the Court is whether the proposed Amendment is fair, reasonable, and adequate. *See* Fed. R. Civ. P. 23(e)(2).

Class Counsel and Pfizer submit that their proposed Amendment is fair, reasonable, and adequate because it facilitates a direct distribution to class members, which they contend represents the optimal use of the money remaining in the Patient Benefit Fund, subject to a hold-back of funds sufficient to cover essential ongoing settlement benefits and expenses. Special Counsel and Public Citizen agree that a direct distribution is the optimal use of the remaining funds and that the proposed hold-back is sufficient funds to cover essential benefits and expenses.

Class action case law and the Settlement Agreement itself require that remaining monies be used to benefit the people whose legal claims led to the settlement and the creation of the fund in the first place—that is, the members of the class. *See* Settlement Agreement, current Paragraph 5.5 (noting that after the Panel determines that medical

research will no longer be fruitful, the remaining funds should be "devoted to some other purpose for the benefit of the Settlement Class").

Now that all diagnostic research sponsored by the Supervisory Panel has come to an end (based on the recommendation of the Panel itself), devoting funds to further research is not a viable option. Other possible uses for the funds would be far less likely to benefit a large number of class members than would a direct distribution. For example, a *cy pres* distribution to a charity that conducts research or other programs generally related to the needs of the class (*e.g.*, a charity that sponsors cardiac research or provides cardiac care to needy people) is unlikely to confer a direct benefit on many, if any, of the remaining class members, who are spread all over the world. In contrast, a cash distribution would confer a direct and immediate benefit on thousands of class members, including all currently registered class members and BSCC Medic Alert members who have been notified and have chosen to register with the settlement administrator.

Similarly, using the remaining monies to set up a fund to pay for implantees' medical expenses or for medical monitoring of some kind is less likely to confer a direct benefit on class members than would a cash distribution. Given the demographic and geographical attributes of the class, most implantees-class members' medical care already is covered by Medicare in the case of U.S. implantees or national health insurances programs in the case of non-U.S. implantees. Moreover, a settlement-administered medical care program, though commendable in some ways, would encounter inefficiencies that a direct distribution program would not. The claims administrator would be required to decide

class members' eligibility for any such new medical benefits, and determinations would have to be made as to whether implantees were already covered by private or public insurance. *See* Settlement Agreement, Paragraph 3.8, and Subsections 5.2.2, 5.6.1.2, and 5.6.1.3 (medical benefits under the *Bowling* settlement are paid only when not covered by private or public insurance). In contrast, a direct distribution to class members would allow *them* to decide what to do with the remaining money. If a class member would prefer to devote the amount received to a charitable donation or toward additional medical care for himself or herself, he or she simply could choose to use some or all of the cash distribution for one or both of those purposes. Moreover, a non-monetary benefits program would continue to require the expenditure of the class members' funds on various administrators, lawyers, and others, while the proposed direct distribution program would devote those funds to the class members themselves.

Accordingly, the Court agrees that a distribution to the class members represents the optimal use of the remainder of the Patient Benefit Fund because it would confer a direct and immediate benefit on thousands of implantees and their loved ones and would allow them to decide how best to use it. The parties originally intended the Patient Benefit Fund to be used primarily for research purposes. However, the Supervisory Panel's determination that research no longer would be useful and that the remaining money in the Patient Benefit Fund should be devoted to other uses beneficial to the class, and the Court's acceptance of that determination, foreclose using the Patient Benefit Fund for research purposes in the future. For the settlement to continue to be—as Judge Spiegel said at the

time he approved it—"a good deal for the members of the Class," the Patient Benefit Fund must be put to a new and different use that *directly* benefits class members.

Under the circumstances that currently exist, the Court is satisfied that permitting money in the Patient Benefit Fund to be distributed directly to class members is fair, reasonable, and appropriate. The Court also is satisfied that, even as it opens the door to a direct cash distribution and relieves Pfizer and Shiley of their obligation to replenish the Patient Benefit Fund, the proposed Amendment preserves other significant payment obligations on the part of Pfizer and Shiley, which will continue to provide tangible benefits and comfort to the members of the class.

As noted above, under the Amendment, Shiley and Pfizer would continue to compensate class members for any individual valve-fracture claims, including paying the additional or alternative benefits referred to in Paragraph 5.6 of the Settlement Agreement. These additional or alternative benefits include payment of $38,000 for all miscellaneous costs and expenses relating to and following hospitalization for qualifying valve replacement surgery; payment for such class member's actual lost income due to time lost from work (up to $1500 per week up to 16 weeks, and longer in the case of a class member who becomes disabled as a result of the surgery) to the extent not otherwise covered by workers' compensation, sick pay, disability, or other benefits; and other payments in the event such class member dies or becomes disabled as a result of qualifying valve replacement surgery. Moreover, as also noted above, claims by eligible class members for

reimbursement of the uninsured costs of qualifying valve replacement surgeries would continue to be paid out of the hold-back.

Accordingly, the Court approves the proposed Amendment to the Settlement Agreement.

2. The proposed distribution also is approved, subject to a hold-back in the amount of $1,619,835.

In addition to proposing the Amendment, Class Counsel, Pfizer, Special Counsel, and Public Citizen also proposed that a significant portion of the remaining settlement funds should be distributed to class members in cash, setting aside a limited reserve fund (*i.e.*, the hold-back) that would be sufficient to reimburse the uninsured costs of future qualifying valve-replacement surgeries as well as cover the costs of the remaining settlement administration.

In response to the notice, Class Counsel received very few written communications from class members regarding the proposed Amendment and distribution. None of the class members who communicated in writing with Class Counsel prior to the fairness hearing objected to or opposed either the Amendment or the distribution. Three class members offered specific written comments.

Dr. Walter Löwe of Germany, an implantee and a retired federal judge, wrote as follows (in German, translated into English) on behalf of himself and his qualifying spouse:

> We hope that the court approves the proposed change in the distribution of the money in the patient assistance fund to the entitled members of the group. If you wish, you may let Judge Black know that we consider the proposed change as appropriate, because the surviving heart valve recipients

> had to endure the fear over many years, that their valve is also prone to breakage and might indeed be broken.

Doc. #3133-2.

Another implantee, Siegfried Leiter, also of Germany, wrote as follows (in English) with respect to the Amendment and distribution:

> … I accept the decision of the majority. I cannot be there on [October] 29, 2015. I get a pension from € 720. Life and work have not been easy, knowing, that the valve could [break] anytime. At the moment my heart [works] 25%. I hope, that the money will mainly be spent for those, who suffered, not for bureaucracy.

Doc. #3135-1.

Dr. Gerard Batts, an implantee from Switzerland, submitted a lengthy statement criticizing much of the way the settlement has been handled. Agreeing with the distribution, Dr. Batts nevertheless characterized the amount he expects class members to receive as "nominal" in comparison to amounts charged by "the lawyers and the Supervisory Panel members" over the years. For example, he stated:

> Apparently there are *c*.7,000 of us BSCC patients left; "the silent majority", many of whom will be living with chronic stress and life-long anxiety knowing an unknown number of sub-standard valves were implanted. Nobody can say if all the sub-standard valves have been identified.
>
> Much of the distress and anger was deflected from Pfizer in the establishment of the settlement and a Supervisory Panel. I do believe that the lawyers appointed and the Supervisory Panel genuinely strove to help patients and families through their often unbearable nightmare. However, when analyzing who gained the most from the settlement over its duration, for me it's clearly the lawyers and the Supervisory Panel members (travel expenses, hotels, time billed for reading and writing scientific papers…). My research team and I published *c*.21 papers in high impact journals without additional payment: it's what scientists do. The Supervisory Panel requested, and was given

> 50,000 USD from the dwindling Patient Benefit Fund to write a summary paper (Harrison *et al.*, 2013) simply to highlight their activities and attempt to justify their management strategies over the decades. With my British sense of humour, I would rename the Fund "The Supervisory Panel and Lawyer's Benefit Fund".
>
> Who gained the least? The very people for whom the settlement was established. Now there appears to be some desire to distribute a nominal amount so those patients who made it through *c*.30 years of chronic stress finally receive some pocket change, if you will.
>
> While I agree with a distribution to patients, it would be helpful for us to know how much of the millions spent (75,000,000-18,641,257 = 56,358,743 USD) was allocated to scientific research in the search for a diagnostic device to save lives? Most lawyers and Supervisory Panel members have been billing the Patient Benefit Fund for decades. When one looks at the nominal amounts predicted to be distributed to patients (Class Counsel's hearing notice, September 2015) perhaps it's appropriate for them all to offer to work *pro bono* from here on in, and distribute a fraction more to those who have gained so little.
>
> In most class actions patients often receive meaningful (life changing) funds early-on in the settlement, and then perhaps additional benefit of a diagnostic device following research efforts with time. I feel at the end of this medical drama us BSCC patients will receive neither.

Doc. 3133-1, pp. 1-2 (emphasis omitted). Dr. Batts added:

> Whilst I support a distribution to patients, research should also continue for a diagnostic device for detection of a Single Leg Separation. There seems to be resistance within the Supervisory Panel (presumably not all members) to update radiographic imaging at the Heart and Vascular Institute, Hershey Medical Center ….

Id. at 3 (emphasis in original). Dr. Batts concluded his submission by stating that, while he agreed with the distribution, he also would favor holding back (1) additional dedicated funds in the amount of $100,000-$200,000 for immediate reassessment and reinstitution of the Hershey study done many years ago, (2) additional dedicated funds in the amount of

$100,000-$200,000 "only for future imaging research" if "in the opinion of the Court circumstances would warrant a Panel member or other imaging specialist to be activated to assess the potential of new imaging technologies as they arise that might benefit Class Members in future years," and (3) an unspecified additional amount for "close monitoring of the BSCC patient cohort … to detect any future spikes in fractures." *Id*. at 4.

Class Counsel also received oral feedback from the remaining class representatives who could be located, namely Emma Wright, Archie Calvert, and Janet Boggess. All of them expressed support for the proposed Amendment and distribution.

The Court agrees with Class Counsel, Pfizer, Special Counsel, and Public Citizen that money from the Patient Benefit Fund should be distributed directly to the members of the class; that each living implantee-class member should receive a share of the distribution, as would each living spouse of an implantee-class member who was married to that implantee as of January 23, 1992 and who is still married to that implantee when the proposed distribution is approved; that the total amount of money available for the spouses' aggregate share would be one-eighth of the total amount of money available for the implantees' aggregate share, just as with the original distribution; and that each qualifying implantee would receive a percentage of the implantees' aggregate share that is similar but not identical to the percentage they received in the original distribution, and each qualifying spouse would receive a percentage of the spouses' aggregate share that is similar but not identical to the percentage they received in the original distribution.

We therefore turn to the appropriate amount of the hold-back. The Settlement Agreement provides that the Patient Benefit Fund is to be used to reimburse eligible class members for the uninsured costs of qualifying valve replacement surgery. However, a relatively small number of class members are eligible for this benefit. Fewer than 50 class members currently qualify for this benefit under the guidelines, and that number is decreasing rapidly. The Supervisory Panel's decision in 2012 not to revise the guidelines ensures that this number will continue to decrease steadily until 2036, when it is estimated that the last qualified class member will become ineligible for this benefit. Given the history of such reimbursements over the course of this settlement, it would be unjustifiable to reserve more than all agree is necessary to cover future reimbursements of uninsured costs of qualifying valve replacement surgeries in the years ahead.

Research sponsored by the Supervisory Panel ceased in 2009, and in 2012 the Panel decided not to revise its guidelines. These developments signaled the end of the Panel's work for all practical purposes. The Court has approved the proposed Amendment in the discussion above. Included in newly approved Paragraph 5.5 is a provision stating that, upon the Panel's recommendation that the remainder of the Patient Benefit Fund be devoted to some other purpose for the benefit of the Settlement Class, "the Court may either terminate the work of the Supervisory Panel or suspend it until, in the opinion of the Court, circumstances warrant further involvement by the Panel or any of its members." Newly approved Paragraph 5.5 also provides that, if the Court opts to terminate or suspend the work of the Supervisory Panel under this Paragraph 5.5, the Court may retain as a

consultant any medical or scientific expert it deems necessary." In 2010, the Supervisory Panel notified Judge Weber that it had concluded that it would no longer be useful to spend the money in the Patient Benefit Fund on research. The Panel confirmed that conclusion in the wake of the Cleveland Clinic study done in 2014. At the hearing on April 24, 2015, the Court in effect suspended the work of the Supervisory Panel when it "ordered that the Supervisory Panel shall remain on stand-by to provide its expertise when requested by the Court." The Court hereby confirms that, pursuant to new Paragraph 5.5, the work of the Supervisory Panel is suspended until, in the opinion of the Court, circumstances warrant further involvement by the Panel or any of its members. The suspension of the Panel's work greatly reduces the amount needed for the hold-back.

Implementing the direct distribution to class members will undoubtedly require additional attorney time, which must be covered by the hold-back. After the distribution, however, there will be far less need for significant attorney time and, thus, far less justification for substantial attorney fees, particularly because Class Counsel and Special Counsel[6] have committed to serving *pro bono* thereafter. Public Citizen's counsel already has shifted to providing services *pro bono*. These developments also greatly reduce the amount needed for the hold-back.

Finally, to determine the appropriate amount of the hold-back, it is necessary that the Court assess Dr. Batts's proposals. As noted above, Dr. Batts suggests that a total of $200,000 to $400,000 be held back for further x-ray imaging research, with a specific

[6] James Capretz is Special Counsel to Class Counsel.

recommendation that $100,000 to $200,000 of that be spent for imaging of class members at the Hershey Medical Center. Doc. #3133-1, at 4. Many years ago, the Supervisory Panel recommended, and Judge Weber approved, funding for an x-ray imaging program at Hershey. The Supervisory Panel later determined that the Hershey program should end, and it did end six years ago. For the reasons that follow, the Panel was correct to end that program, and Dr. Batts's suggestions for reviving it are rejected.

Before explaining why, on purely scientific grounds, the Hershey program (or any other imaging program) should not be reinstated, two preliminary points warrant mention. First, Dr. Batts appears to be asking this Court to order the diversion of funds to reinstitute a Hershey program and for other future imaging research. This Court, like any federal court, lacks that power. Class action settlements, and amendments to them, are matters of contract between the parties, with courts having up or down approval authority, but nothing more. *Evans v. Jeff D.*, 475 U.S. 717, 726 (1986) ("[T]he power to approve or reject a settlement negotiated by the parties before trial does not authorize the court to require the parties to accept a settlement to which they have not agreed."). Thus, although a court may make suggestions for amendments when it believes that the pending settlement is not approvable, it lacks power under Rule 23(e) to order particular settlement terms. *Id.* at 727.

Second, Dr. Batts's suggestion would reallocate money currently proposed to be distributed to individual class members. If Dr. Batts's suggestion were adopted, the total amount of money available to class members would be smaller than the amount set forth in the notice previously sent to the class members. Though the total amount would be

reduced by a relatively small amount, before this Court considers whether Dr. Batts's proposals should become a part of the settlement, class members arguably would be entitled to a revised notice and another opportunity to object and explain why the money should go to them and not to imaging programs.

In any case, Dr. Batts's proposals are unwarranted on their own terms. The purpose of imaging technology is to determine whether a BSCC valve inside a patient's chest contains a single-leg separation ("SLS"). SLS is a precursor to a potentially catastrophic outlet strut fracture ("OSF"). OSF is either fatal or results in serious injuries. So, the overall theory of a successful imaging program is that, *if* the technology can reliably diagnose SLS in living patients implanted with BSCC valves, patients who test positive for SLS may then undergo valve replacement surgery and thereby avoid OSF.

But as the Supervisory Panel told Judge Weber in 2010, the Hershey program failed because it could not show that the imaging technology had the capacity to reliably diagnose SLS in BSCC patients:

> The panel has never seen sufficient data from th[e Hershey] study to verify the validity of the x-ray imaging technology. Without such sensitivity and specificity data, the panel has little confidence in the imaging result as a diagnostic device or tool for patients or their physicians. The results of the Hershey imaging study have not satisfied the panel that the method is reliable for differentiating intact valves from those with SLS of an outlet strut.

Doc. #2670, at 13 (Jan. 15, 2010).

As the Supervisory Panel emphasized in its submission, a key problem with the Hershey study was that very few patients (39) were willing to participate and far fewer still

(7) later had their valves explanted. *See id.* The latter number is critical because only by explanting valves and examining them for SLS can anyone know whether the technology is capable of accurately detecting valves with SLS. These low numbers are not surprising. Despite the Supervisory Panel's efforts to enroll class members, very few class members, many of whom are elderly and infirm, wanted to expose themselves to radiation in an effort to test unproven technology. Moreover, given the serious risks of open-heart surgery (particularly for older patients), only a tiny number of class members, understandably, wanted to take on those risks.

If the Hershey program were revived, or a program like it were instituted, the number of study participants and explantation surgeries would likely be even smaller than they were in the original program (as noted, 39 and 7, respectively). Since the Hershey program ended more than six years ago, with the passage of time, the number of living class members has steadily declined. Moreover, as Dr. Batts acknowledges (Doc. #3133-1, at 2), thankfully, very few outlet strut fractures have occurred in recent years. *See generally* Doc. #2670, at 5 (discussing this phenomenon). Moreover, as class members get older, it makes less sense for them to undergo valve replacement surgery because open-heart surgery becomes riskier with age. *Id.* This is why the Panel has determined that, as of 2015, only 46 individuals in the entire class would benefit from valve replacement surgery—that is, under the Panel's valve replacement guidelines, there are only 46 class members for whom the risk of OSF outweighs the risk of valve replacement surgery. *See* Exhibit A to

Joint Motion (Doc. #3137) (chart showing the estimated number of class members eligible for valve replacement surgery year-by-year).[7]

For all of these reasons, it would be impossible to recruit enough class members to validly test x-ray technology aimed at detecting SLS valves in living class members. On that ground alone, Dr. Batts's suggestions are rejected.

One other consideration is even more important. Dr. Batts's proposal appears to assume that, other than draining the fund of several hundred thousand dollars, there could be no possible harm to class members by reinstating the Hershey program or a program like it. Using the money for research, Dr. Batts believes, may not help class members, but it cannot hurt them. But that assumption is incorrect, as the results of the original Hershey study demonstrate. The imaging technology used at Hershey did not exhibit the level of accuracy that modern science demands. That technology failed to predict the valve's correct status for at least *four* of the seven values explanted during surgery. *See* Doc. #2670-7 (Jan. 15, 2010).[8] Most troubling is that among the study's four clear errors was a *false positive*—in other words, one valve was imaged as "Probably SLS," but, in fact, it was a

[7] Even this small number (46) significantly overstates the number of class members who would *actually* benefit from valve replacement surgery. Under the Panel's valve replacement guidelines protocol (Doc. #290), the Panel was required to assume that any class member undergoing surgery would be in optimal health and would undergo surgery at an optimal surgical facility. But the class members—most of whom are elderly and all of whom suffer from at least some form of heart disease—are not in optimal health, and many of them do not have access to an optimal surgical facility.

[8] It is appropriate to say "at least" because, besides the four valves that indisputably were mischaracterized by the imaging technology, a fifth valve was viewed as only "minimally suspicious" upon x-ray, yet it had SLS upon post-surgical examination.

perfectly good, intact valve. *See id.* To be clear: *This patient risked dying from inherently risky open-heart surgery for no reason.* In addition, one other error also could be considered a false positive—it was imaged as "suspicious," but, in fact, it was completely "intact." *See id.* In sum, based on the results of the original Hershey program, reinstituting the program could be dangerous, risking more false positives for class members and thus post-operative death or serious injury.

For all of these reasons, this Court defers to the Panel's expertise and rejects Dr. Batts's proposals.

Having considered the arguments presented in the Joint Motion and at the hearing, and the views of the class members, the Court accepts the unanimous assessment of Class Counsel, Pfizer, Special Counsel, Public Citizen, and the Special Master/Trustee that the proposed hold-back of $1,619,835 would be more than sufficient to cover the reasonable and foreseeable (a) costs of reimbursing qualified class members' uninsured expenses related to explant surgeries under subsection 5.2.3, including those who qualify under the Supervisory Panel's guidelines and those later diagnosed with single-leg fractures; (b) fees and expenses of the Settlement Administrator; (c) fees and expenses of the Special Master/Trustee; (d) fees for any necessary tax return preparation and accounting and for a biennial review of the remaining funds by a qualified outside accounting firm; (e) costs associated with administering, implementing, and/or enforcing the terms of the Settlement, including any additional expenses of the Supervisory Panel or its members and any further work that the Court might ask of the Panel or any of its members; and (f) fees and expenses related to the

distribution. This hold-back will cover the foregoing expenses and any other costs associated with carrying out the purposes of the Settlement Agreement in future years.

Accordingly, the Court hereby (1) approves the proposed Amendment and the proposed distribution, (2) determines that $1,619,835 is an appropriate amount to be held back for the purposes mentioned in new Paragraph 5.5(a) through (f), (3) orders that this amount be held back for these purposes, and (4) instructs the Special Master/Trustee and the administrator to carry out the distribution forthwith.

IT IS SO ORDERED.

Date: November 16, 2015

s/ Timothy S. Black
Timothy S. Black
United States District Judge